FEB 12 2014

510(k) Summary Report:

C-Box® PEEK Cervical IBF System

Company: Innovasis, Inc.
614 E. 3900 South
Salt Lake City, UT 84107

Contact: Marshall C. McCarty
Phone: (801) 261-2236
mmccarty@innovasis.com

Trade Name: C-Box® PEEK Cervical IBF

Common Name: Intervertebral fusion device with bone graft, cervical

Classification: Regulation No.: 21CFR 888.3080
Class 2
Product Code: ODP
Review Panel: Orthopedic ASDB
Applicable Standards:

- ASTM F560-08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ASTM F983-86 Standard Practice for Permanent Marking of Orthopedic Implant Components
- ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications
- ASTM F2077-11 Test Methods for Intervertebral Body Fusion Devices
- ASTM F2267-04 (Reapproved 2011) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
- ISO 17665-1: 2006 Sterilization of Healthcare Products – Moist Heat – Part 1 Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

Substantially Equivalent Devices:

K082801	Phantom™ Plus Cage System	(US Spine)
K130699	Aleutian Spinal System	(K2M)
K120486	AVS AS PEEK Spacer	(Stryker)
K103660	Breckenridge Cervical IBF	(Lanx)

Device Description: *C-Box® PEEK Cervical IBF*

The single use devices are rectangular in shape with rounded corners and are offered in a variety of different heights to accommodate patient anatomy. The design features include:

- Proportional sizing for the cervical spine
- 6° lordosis
- Manufactured with Invibio PEEK OPTIMA® polyetheretherketone
- Large central window for bone autograft material
- Radiolucent
- Tantalum markers to facilitate and verify device placement
- Custom position instruments to facilitate proper implant placement
- Proud tooth design on superior and inferior surfaces to resist migration

Performance Data: (Non-clinical)—Performance testing per ASTM F2077-11 and F2267-04 for Static Compression, Static Compression Shear, Static Torsion, Dynamic Compression, Dynamic Compression Shear, Dynamic Torsion, Subsidence and Expulsion, indicates that the *C-Box PEEK Cervical IBF* is substantially equivalent to the predicate device.

Materials: The implants are machined from medical grade polyether-etherketone (Invibio PEEK Optima®) per ASTM F-2026. The radiographic markers meet ASTM F-560 for unalloyed Tantalum.

Intended Use: The *C-Box PEEK Cervical IBF* device is intended for use in Anterior Cervical Discectomy and Fusion (ACDF) procedures.

Users of these products are limited to physicians trained in orthopedic surgery. Clinical locations include hospitals and surgery sites equipped to perform spinal surgery.

Indications for Use: The Innovasis *C-Box PEEK Cervical IBF* device is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

This device is to be used in patients who have had six weeks of non-operative treatment. The *C-Box* device is to be used with supplemental fixation, such as the Innovasis *Opteryx® Cervical Plate System*. The *C-Box* device is intended to be used with autograft bone and is to be implanted via an open, anterior approach.

Contraindications (Exclusions for Use):

Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.

Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant.

Conditions that may place excessive stress on the bone and implant, such as severe obesity or degenerative diseases are relative contraindications. The decision whether to use these devices under these conditions must be made by the physician taking into account the risks versus the benefits to the patient.

Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bone healing and may be at a higher risk of implant failure.

Basis for Substantial Equivalence:

The C-Box PEEK Cervical IBF has been subjected to risk analysis, engineering analysis and testing to recognized standards and has been shown to be substantially equivalent to the predicate devices, K082801 Phantom™ Plus Cage System, K130699 Aleutian Spinal System, K120486 AVS AS PEEK Spacer, and K103660 Breckenridge Cervical IBF.

- Design configurations are substantially equivalent.
- Applied mechanical loads are substantially equivalent.
- Product sizes and shapes are substantially equivalent.
- Materials used are equivalent.
- Biocompatibility requirements have been demonstrated.
- Manufacturing and processing methods are substantially equivalent.
- Shelf life is equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Innovasis, Incorporated
Mr. Marshall McCarty
Director Quality Affairs/Regulatory Affairs
614 East 3900 South
Salt Lake City, Utah 84107

Re: K132991
Trade/Device Name: C-Box® PEEK Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 16, 2014
Received: January 22, 2014

Dear Mr. McCarty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent D Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 Indications for Use Statement

510(k) Number: k132991

Device Name: C-Box® PEEK Cervical IBF System

INDICATIONS FOR USE are as follows:

The Innovasis *C-Box PEEK Cervical IBF* device is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies.

This device is to be used in patients who have had six weeks of non-operative treatment. The *C-Box* device is to be used with supplemental fixation, such as the Innovasis *Opteryx®* *Cervical Plate System*. The *C-Box* device is intended to be used with autograft bone and is to be implanted via an open, anterior approach.

Prescription Use X OR Over-The-Counter-Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices